EXHIBIT 1

Establishment Inspection Report	**FEI & CFN:**	**2017865**
St Jude Medical CRMD	**EI Start:**	**06/08/2009**
Sylmar, CA 91342-3577	**EI End:**	**07/08/2009**

SUMMARY

This was a For-Cause QSIT inspection of a high-risk medical device manufacturer of implantable defibrillators, pulse generators, and their leads. These devices are subject to Device Tracking Regulations. The FACTS assignment #1042352, initiated by CDRH, HFZ-341, was to obtain documentation and evidence of the firm's Corrective and Preventive Actions (CAPA), Complaint Handling, Medical Device Reporting (MDR), and Risk Analysis procedures as they related to perforations with the Riata and Durata family of leads. Compliance Program 7382.845, Inspection of Medical Device Manufacturers, was followed. The devices covered during the inspection were the Riata and Durata family of leads and the Medical Device Profile Classes were MTL, GSP and PRF.

The previous baseline QSIT inspection was conducted on 06/9 -13/2008. That inspection found no objectionable conditions and was classified NAI.

The current team inspection focused on the two QSIT subsystems, Design Control and Corrective and Preventative actions related to perforations with the Riata and Durata family of leads Additionally, the areas for vendor qualifications, receiving inspections, internal audit, equipment maintenance, employee training were also covered. The inspection revealed the firm had deficiencies in the areas of handling complaints and making MDR determinations; and having deficient CAPA and receiving procedures. Additionally, the firm failed to follow its procedure for product design developments of Riata and Durata leads. An eight-item FDA-483 was issued to the firm's management on 7/8/2009. They declined annotations on the FDA-483, but promised to submit a written response to the Los Angeles District Office within 15 days.

Documentary Sample 421779 was collected to establish interstate commerce. The firm management declined to sign an affidavit explaining it was company policy not to read, sign or listen to it. No other refusals were encountered.

ADMINISTRATIVE DATA

Inspected firm:	St Jude Medical CRMD
Location:	15900 Valley View Ct Sylmar, CA 91342-3577
Phone:	818-362-6822
FAX:	(818)833-4968
Mailing address:	15900 Valley View Court Sylmar, CA 91342
Registration status:	Active FDA registration for 2008 as medical device manufacturer

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Hours of operation:	Office hours: 9am to 5pm, Monday - Friday. Production hours (b) (4) Monday – Friday (b) (4)
Name and title of person to whom Federal credentials were presented. FDA-482 was issued	Kathleen M. Chester – Senior VP Regulatory Affairs & QA
FDA-483 was issued	Eric S. Fain – President of St. Jude CRMD
Dates of inspection:	6/8/2009, 6/9/2009, 6/10/2009, 6/11/2009, 6/12/2009, 6/16/2009, 6/17/2009, 6/18/2009, 6/22/2009, 6/24/2009, 6/25/2009, 7/8/2009
Days in the facility:	12
Participants:	Kelvin Cheung, Investigative Engineer (Lead) Bradley Q. Quinn, CSO (CAPA) Roberta A. Sullivan, Nurse Consultant (Complaints & MDRs)

ADMINISTRATIVE DETAILS:

This was a pre-announced team inspection consisting of myself, Kelvin Cheung, Los Angeles District, Consumer Safety Officer Bradley Q. Quinn, CSO, CDRH/Office of Compliance/Division of Enforcement B/Cardiac Rhythm and Electrophysiology Device Branch and Nurse Consultant Roberta A. Sullivan, PEB/DPS/OSB/CDRH.

We primarily followed the FACTS assignment covering the firm's Corrective and Preventive Actions (CAPA), Complaint Handling, Medical Device Reporting (MDR), Risk Analysis procedures and design developments of Riata and Durata leads. CSO Quinn was responsible for the area in the CAPA and risk analysis of the Riata and Durata leads and Ms. Sullivan was responsible for reviewing the firm's complaint and MDR system. I covered the areas in the design developments of Riata and Durata leads.

HISTORY

St. Jude Medical, Cardiac Rhythm Management Division (CRMD), Sylmar, California is currently registered as a medical device manufacturer under FEI 2017865. The CRMD is an operating unit under St. Jude Medical Inc., a supplier of a wide range of critical care cardiovascular products.

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St. Jude CRMD has an ongoing history of commercially manufacturing and sponsoring clinical studies for pulse generators, implantable cardiac defibrillators (ICDs), and their associated endocardial leads and programmers.

St. Jude Medical Inc. was founded in 1976. Its headquarters is located at One Lillehei Plaza, St. Paul, MN 55117. Mr. Daniel J. Starks is President, Chief Operating Officer and Chairman of the Board.

Dr. Eric S. Fain, MD, replaced Mr. Michael J. Coyle as President of CRMD in July 2007. Dr. Fain reports to Mr. Starks while maintaining offices at the Sylmar and Sunnyvale sites. The Sylmar site is the headquarters for CRMD.

All FDA post inspectional correspondences should be directed to:

Dr. Eric S. Fain, President, St. Jude Medical CRMD
15900 Valley View Court,
Sylmar, CA 91342.

The Sylmar complex consists of the primary plant on Valley View Court and some leased facilities within two blocks walking distance. Approximately (b) (4) individuals are employed at the Sylmar complex. The total area of all the Sylmar facilities is approximately (b) (4) with about (b) (4) sq. ft. accounted by the plant itself. The plant has two stories. The ground floor is mainly for production and the second floor is for offices. **Exhibit #1** is the floor plan for the ground floor of the plant. The Sylmar facility operates (b) (4) Monday through Friday. Normal business hours are 8:00 am – 5:00 pm, from Monday through Friday.

The following are other facilities that are operated under St Jude Medical CRMD:

The CRMD facility located at 701 East Evelyn Avenue, Sunnyvale, CA 94806 does no commercial manufacturing of any kind. Sunnyvale houses the research and development (design) group for the ICDs plus the regulatory submissions group for the ICD products. Sunnyvale is the initial contact for customer complaints and technical support for the ICDs. Failure analysis of explanted ICDs is done and maintained in Sunnyvale. Sylmar does the failure analysis for the ICD leads. The Sunnyvale facility responsible for filing all MDRs for ICD and ICD leads.

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The CRMD facility located at 8300 East Pacesetter Way, Scottsdale, AZ 85255 manufactures what is known as the hybrid, the key circuitry component in the pulse generators and ICDs. The hybrid contains the microprocessor and the memory that controls the pulse generators and ICDs. Scottsdale is operated as an extension of the Sylmar plant.

The CRMD facility at 235 Financial Blvd., Liberty, SC 29657 manufactures the high voltage capacitors used in the defibrillators. These capacitors are only made for CRMD and this is the only product made at the Liberty site. Liberty is operated as an extension of the Sylmar plant.

There is a CRMD manufacturing site abroad at Veddestavagen 19, Jarfalla, SE-17584, Sweden for pulse generators and leads that are exclusively for non U.S. markets.

The CRMD manufacturing site (3006705815) located at Lot A Interior- #2 ST, Km 67.5, Santana Industrial Park, Arecibo, Puerto Rico, 00612 manufactures pulse generators and their leads under CRMD.

INTERSTATE COMMERCE

The St Jude CRDM sales for 2008 were approximately (b) (4) dollars. General promotion is performed through trade shows and direct sales marketed to physicians. Distribution is nationwide and international. Finished product is stored a short walk away from the Valley View plant (b) (4) facility at (b) (4) (b) (4) The firm ships its devices to domestic customers through FedEx. Over (b) (4) of sales were outside of California.

Documentary Sample 421779 was collected to establish interstate commerce. It showed St. Jude Medical, Inc. received soft tip components from (b) (4) of (b) (4) and made an active Durata dual shock 7F soft tip curved RV lead, model 7120/65, S/N AHA18963 with the aforementioned soft tip component and then shipped the finished device to (b) (6) via FedEx, tracking # (b) (4) on or about 6/10/2009.

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JURISDICTION

St. Jude CRMD has an ongoing history of commercially manufacturing and sponsoring clinical studies for pulse generators, implantable cardiac defibrillators (ICDs), and their associated endocardial leads and programmers. These are Class III PMA medical devices and clinical studies involving human subjects that are subject to Food, Drug & Cosmetic Act.

The latest models of ICDs are known as the *Current* and the *Promote*. Their associated leads are known as the *Durata* and the *Riata*. The latest models of the pulse generators are the *Zephyr* and the *Victory*. Their primary associated lead is known as the *Tendril*. CRMD estimates it has over (b) (4) implant systems in living patients.

Product information is available online at the firm's corporate website: www.sjm.com.

PERSONS INTERVIEWED AND THEIR RESPONSIBILITIES:

We displayed our Credentials and issued a Notice of Inspection to Ms. Kathleen M. Chester, Vice President of Quality Assurance and Regulatory Affairs. Ms. Chester was in charge because Dr. Fain was away on business. (Dr. Fain introduced himself to us on 06/10/09.) Ms. Chester then directed key members of her staff (Mr. Mr. Philip Tsung and Mr. Nestor Kusnierz) to assist us during the entire inspection. Ms. Chester did not actively participate in the inspection but attended the closing meeting on 7/8/09. Ms. Chester is the firm's management representative for the Sylmar facility.

Mr. Philip Tsung, Sr. Director of Quality Assurance for Sylmar, was a primary participant during the inspection. Mr. Tsung arranged for interviews and had his personnel deliver documents. He has worked for St. Jude for over 6 years and he reports directly to Ms. Chester.

Mr. Nestor Kusnierz, Director of Regulatory Compliance, was a primary participant during the inspection. Mr. Kusnierz is a 25 year veteran with St. Jude. His primary task is to assure the inspection runs smoothly and within the firm's regulatory procedures. He answered questions regarding complaints and MDRs. He reports to Mr. Tsung.

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Mr. Ben Gomperz, Program Manager, provided information on the design projects for the Riata and Durata leads. He is a 14 year veteran employee and reports to Chris Jenney, Director of Brad & Tachy Leads Development.

Mr. Vishnu Charan Naidu, Director of Lead Development & Operations, led a detailed walk through the high voltage lead manufacturing area and provided explanations on the curing process and equipment maintenance. He reports to Mr. Ben Khosravi, Executive Vice President of Product Development and Leads Operations.

Exhibit 2 is an organizational chart for key management of CRMD

MANUFACTURING/DESIGN OPERATIONS

The current team inspection focused on the two QSIT subsystems, Design Control and Corrective and Preventative actions related to perforations with the Riata and Durata family of leads Additionally, the areas for vendor qualifications, receiving inspections, internal audit, equipment maintenance, employee training were also covered. Questions in FACTS assignment #1042352, were addressed under the sections of Complaints, CAPA and Design Controls.

COMPLAINTS (Covered and written by Roberta A. Sullivan)

The firm has written procedures for product complaints **(exhibit #3)**, and Medical Device Reporting **(exhibit #4)**. According to Mr. Kusnierz, the Sunnyvale facility is the initial contact for customer complaints and technical support for the ICDs. Failure analysis of explanted ICDs is done and maintained in Sunnyvale. Sylmar does the failure analysis for the ICD leads. The Sunnyvale facility responsible for filing all MDRs for ICD and ICD leads.

Exhibit #5 is a CD-ROM consisting of an Excel spreadsheet for all complaints for Riata/Durata since 2002 that Mr. Kusnierz provided to us during the inspection. This represented the time period from device approval through June 9, 2009 and totaled 8,463 complaints. For all complaints identified as "perforation, patient", it was indicated that an MDR had been submitted. The FDA adverse event database contains 3,689 MDRs from the firm for these devices during this time period. As of June 10th, 2009 FDA has

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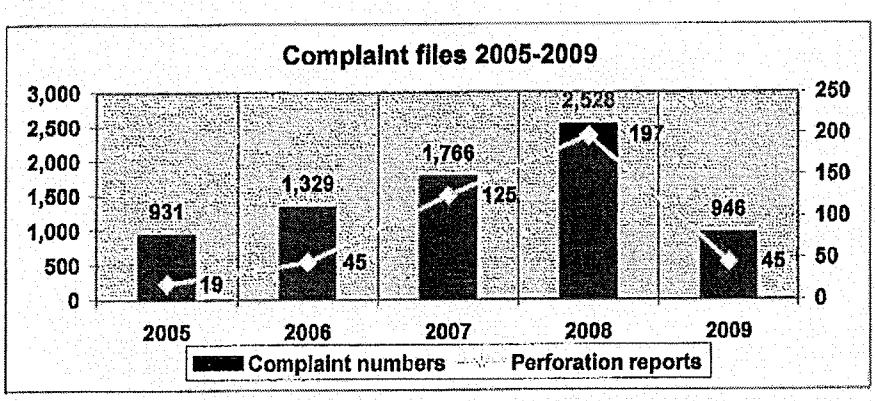
received 10 reports perforation with patient death for either Riata or Durata devices. This was confirmed in the Maude database through 6/9/09. **Exhibit #6** is a summary of MDRs through February 2009 for Riata & Durata that were related to perforations.

Review of 8,400+ electronic complaint files for Riata/Durata from 2005-2009 (Excel spreadsheet by year) showed the highest number of both overall and perforation reports in 2008. As a percentage of total complaints, perforations rose from (b) (4) in 2005 to almost (b) (4) in 2008.



Prior to the inspection, 32 MDRs were identified from the adverse event database as possible Riata perforation events, and the complaint files for these were requested and reviewed during the inspection. Note that these complaint files had to be transmitted to the Sylmar inspection location from their Sunnyvale facility. Review of these complaint files and the associated Medical Device Reports (MDRs) revealed that in some cases the manufacturer has failed to submit MDR reports containing all information reasonably known to them in accordance with the provisions of 21 CFR 803.50(b). Specifically, the complaint files show that complainants reported perforation adverse events for the Riata/Durata device, but these events were not reported as "perforations" in the associated MDRs submitted to FDA by the manufacturer. Perforation was not identified in the submitted 3500A either in the patient or device problem codes (**Observation #1**). A sampling of 8 complaints from the firm's 2008 worksheet that were identified as "capture anomaly" , "dislodgment" or "patient discomfort" and also underwent tip-stiffness testing, were retrieved from the MAUDE database by device serial number for review. Six of these in fact described a suspected perforation, and it could not be ruled out as possible for the other two events. Postmarket surveillance by FDA is hampered when mandatory reporting terminology is not clear, accurate and consistent.

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Review of the Durata IFU finds no precautions or instructions for prevention of perforation events. Although perforation events continue to occur, the firm has not provided new instructions or precautions for lead handling and perforation prevention since the May 2007 paper for use by field representatives (This is a labeling issue).

The Corrective and Preventive Action for ICD lead perforations (PIR 04-003) references factors, related to perforation events including physician implant technique, patient variables and potential lead design. However, failure analysis was limited to tip-stiffness testing and only in cases when product was returned. For all perforation events with returned product analysis, tip-stiffness was found to be within specifications, and in no cases the device was found outside of manufacturing specifications for stiffness. Per 21 CFR 803.50, the manufacturer is responsible for conducting an investigation of each event and evaluating for the root cause. Laboratory tip testing of returned product cannot confirm or rule out lead perforation, which is a clinical diagnosis.

Complaints representing events that are MDR reportable were not promptly reviewed, evaluated and investigated by the designated individual per 21 CFR 820.198(d), and MDRs were not submitted within the mandatory reporting timeframes required by 21 CFR 803.50 for device manufacturers. For example, MDR # 2017865-2008-00444 provides a manufacturer aware date and perforation event in 2003. The 3500A was submitted without explanation to FDA on January 10, 2008. Similarly, MDR # 2017865-2008-00447 provides a perforation event date and manufacturer aware date in 2004, but the 3500A was also submitted without explanation to FDA on January 10, 2008. These were submitted significantly past the mandatory reporting timeframes. **See Observation #2 for details.**

Training on complaint handling with field staff may need improvement. Many products are returned for analysis without an associated complaint, although obtaining the reason for explant would not be expected to be difficult for the field staff attending procedures. **See Observation #1 for details.** Additionally, review of the MDRs submitted from 2007 through June 2009 found no evidence that the events described in the following medical or scientific literature were submitted to FDA as required by regulations and company procedures, if they were aware.

- Life-threatening perforation of a defibrillation lead. Hermanides R, Ottervanger J, Elvan A, Ramdat Misier A. Neth Heart J. 2009 Mar;17(3):113-4

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- Late perforation of a defibrillator lead managed by percutaneous, intravenous extraction. Sekar B, Tapp L, Chalil S, Marshall H, Leyva F. Europace. 2009 Feb;11(2):255-7
- Timing of delayed perforation with the St. Jude Riata lead: a single-center experience and a review of the literature. Danik SB, Mansour M, Heist EK, Ellinor P, Milan D, Singh J, Das S, Reddy V, D'Avila A, Ruskin JN, Mela T.Heart Rhythm. 2008 Dec;5(12):1667-72. Epub 2008 Sep 16.
- Increased incidence of subacute lead perforation noted with one implantable cardioverter-defibrillator. Danik SB, Mansour M, Singh J, Reddy VY, Ellinor PT, Milan D, Heist EK, d'Avila A, Ruskin JN, Mela T.Heart Rhythm. 2007 Apr;4(4):439-42. Epub 2007 Jan 7
- Concerns about the Riata ST (St. Jude Medical) ICD lead. Vlay SC.Pacing Clin Electrophysiol. 2008 Jan;31(1):1-2.
- Danik SB, Mansour M, Singh J, et al. Increased incidence of subacute lead perforation noted with one implantable cardioverter-defibrillator. Heart Rhythm 2007;4:439–442.

CORRECTIVE AND PREVENTIVE ACTIONS (Covered and written by Bradley Q. Quinn)

We reviewed the following CAPA-related procedures:

- SOP 3.3.5 – Corrective Action and Preventive Action Procedure, Revision N **(Exhibit #7)**
- SOP 4.7.2 – Global Risk Management Procedure, Revision H **(Exhibit #8)**

We verified that the firm had procedures in place that met the requirements of 21 CFR 820.100(a). However, SOP 4.7.2 – Global Risk Management Procedure **(Exhibit #8)**, which defines the Risk Management process as it relates to clinical risk in new product development and throughout the product life cycle, was inadequate in that the procedure did not establish a methodology for obtaining a Probability of Occurrence used in Risk Evaluations. The inadequacy is demonstrated in the firm's three (3) Risk Analysis that were performed as part of the firm's Product Improvement Request (PIR) file, PIR 04-003 **(Exhibit #9)**. **Please refer to Observation 3.**

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We also requested a list of all CAPAs (PIRs) opened since 2002 (**Exhibit #10**). From that list, we requested the firm provide PIRs related to High Voltage (HV) Leads. The firm provided the following PIRs:

- 09-005 – Helix extension retraction failure due to the spring popping out of its location and getting jammed between the header coupling and stopper
- 09-001 – Cable Fracture under Strain Relief Coil DF-1 leg
- 07-006 – Outer Coil Fractures at IS-1 Connector Ring
- 06-014 – Hypot Failures in Riata ST Leads Manufacturing
- 06-012 – Riata Coil Fracture at Inner Coil Shaft
- 06-005 – Missing DF-1 Crimps in HV Lead Manufacturing
- 06-004 – Swapped DF-1 Labels in HV Lead Manufacturing
- 06-003 – Riata Lead With Incorrect Conduction Paths
- 05-016 – Riata Integrated Bipolar IS-1 Connector Dielectric Strength Improvement
- 05-009 – Riata Lead Abrasion (**Exhibit #11**)
- 04-006 – Insufficient crimp on RV shock coil termination ring employed on the Riata Integrated Bipolar Leads seen in Manufacturing
- 04-003 – Riata Perforation (**Exhibit #9**)
- 03-006 – Riata Lead Cable Coating Abrasion
- 02-004 – Riata, Missing Weld, DF-1 Conn. Pin

[Bradley Quinn reviewed PIRs 04-003, 09-001, 05-009, 06-005. PIRs 09-001, 05-009, and 06-005 appeared to be adequate. PIR 04-003, Riata Perforations, (**Exhibit #9**) contained three (3) Risk Analyses dated April 28, 2005, October 18, 2007, and March 16, 2009. Each Risk Analysis used a different method for obtaining a Probability of Occurrence. In the April 28, 2005, analysis the firm obtained a Probability of Occurrence value by dividing the number of reports of perforation by the number of leads that had been manufactured. In the October 18, 2007, analysis, the firm obtained a Probability of Occurrence value by dividing the number of reports, both returns and complaints, by the number of leads sold world-wide. In the March 16, 2009 analysis, the firm obtained a Probability of Occurrence value by dividing the number of confirmed serious injuries by the number of leads sold world-wide. Please see Observation 3 for details.]

Additionally, we requested the firm's World Wide Product Disposition Review Board (WWPDRB) meeting minutes (**exhibit #12**) where Riata Lead perforations were discussed. The dates for these WWPDRB meetings were:

- August 22, 2006
- November 7, 2006

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- February 6, 2007
- May 15, 2007
- July 24, 2007
- November 27, 2007
- March 4, 2008
- May 28, 2008
- August 28, 2008
- December 10, 2008
- February 27, 2009
- May 29, 2009.

The WWPDRB meetings were held to discuss issues that had a Criticality value of four (4) or five (5). The meeting minutes consisted of a brief summary, list of participating members, and PowerPoint slides used for the presentation of issues. **(Assignment Specific Question #)**

DESIGN CONTROL (Covered and written by Kelvin Cheung)

During the inspection, I covered the design projects for the original marketed Riata leads models 1580 and the newest marketed Durata leads, models 7120. These are the most popular leads that the firm has distributed among other Riata and Durata models:

Model #	# Distributed	Marketed since
Riata, model 1580	(b) (4)	March 2002
Durata, model 7120		September 2007

The Riata 1580 was initially developed under the project for "Vectra Tachy Active Fixation Lead. The conceptual design review was completed in (b) (4) but the critical design review and the product development plan were not officially approved by top management until (b) (4) There were (b) (4) product development plans (PDP) in the DHFs. The initial one was approved by the management on or about (b) (4) An updated plan was released on 9/24/01 with new design improvements after prototype units failed the pinch load test in the design verifications. The new design improvements were described in the updated PDP and the Design Verification Test Report, ER2061-0023

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Rev. 1 dated 1/18/2002. The procedure for "Global Product Development Protocol" Revision C (**exhibit #13**) was used mainly during this design project. The deliverables and design reviews are described in the procedure, sections. 5 - 7 and the specific responsibilities are mention in the tables of the PDP.

Mr. Gomperz who provided the design control information during the inspection was listed as the Development Engineer for the Riata project and the Program Manager for the Durata project.

The following risk analysis and validations were covered during the review of the design history file for the Riata, model 1580:

Conceptual Design Review Report dated (b) (4) **(exhibit #14)**
Product Development Plan, Doc #200102-103, revision 2.00 dated (b) (4) **(exhibit #15)**
Product Development Plan, Doc #200102-103, revision #2.01 dated (b) (4) **(exhibit #16)**
Hazard Analysis #009
FME 039 dated (b) (4)
FMECA 053 dated (b) (4) **(exhibit #17)**
FMECA 053 Addendum 001 dated (b) (4) **exhibit #18)**
Design Verification Test Report, ER2061-0023 Rev. 1 dated (b) (4)
Qualification Test Report 1403 dated (b) (4) **exhibit #19)**

During the review of the initial Product Development Plan, Doc #200102-103, revision 2.00 dated 2/8/00 **(exhibit #15),** I noticed that the plan initially described the use of Gantt chart for scheduling and monitoring deliverables of the design project. When I asked Mr. Gomperz to provide me with the Gantt chart that was generated at the end of the design project, he could not locate one in the DHF. He later stated the procedure did not require the Program Manager to use a Gantt chart for tracking the progress of the design project. Since there was no Gantt chart available and the project was at least 8 year old. I told the firm's management that it became impossible to review the progress of the design project without a completed Gantt chart/table.

The firm has written procedure to cover design changes. Mr. Gomperz stated the firm started documenting product specifications and manufacturing procedure during the development phase. The review of the design changes revealed although the firm

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followed the change procedure, the reasons and justifications for changes were not properly documented for couple occasions. See **Observations #8** for details.

Exhibit #20 is a list of design related changes for Riata lead, model 1580, provided by Mr. Kusnierz during the inspection. According to Mr. Kusnierz, since this is a PMA device, all changes described on the list should have been reported to FDA through the annual report or PMA supplement.

The design project for Durata, formerly named "Riata STS Optim, model 7120 was selected for review during the inspection. The Durata model 7120 is an active true bipolar dual coil transvenous tachyarrhythmia lead. The design project started in (b) (4) and was divided into three submissions: a) softer tip b) softer tip and curved RV and c) design improvement. The procedures for "Global Product Development Protocol" Revisions D & E **(exhibit #21)** were used for this design project. **Exhibit #22** is "Key Milestone Update" that Mr. Gomperz created for me during the inspection. The following documents were reviewed during the inspection:

Product Development Plan, revision 1, dated (b) (4) **(exhibit #23)**
Riata Leads Risk Management Report, Rev 011 dated 6/20/07 for softer tip
Riata Leads Risk Management Report, Rev 012 dated 8/10/07 for curved RV
Concept Design Review dated (b) (4) **(exhibit #24)**
Core Team Weekly Minutes
Critical Design Review (DR2) **(exhibit #25)**
Critical Design Review (DR3) **(exhibit #26)**
Quality Assurance Test Report, Riata STS Optim (Silicon tip only) QTR 2117
Quality Assurance Test Report, Riata STS Optim (Silicon tip & curved RV) QTR 2164

I reviewed the Concept Design Review, Critical Design Review (DR2) and Critical Design Review (DR3) and verified all open issues discussed during the review meetings had been addressed and closed with proper actions. Additionally, I also reviewed the Quality Assurance Test Report, Riata STS Optim (Silicon tip only) QTR 2117**(exhibit #9)** and Quality Assurance Test Report, Riata STS Optim (Silicon tip & curved RV) QTR 2164 **(exhibit #9)** and all prototype units passed the acceptance criteria. No problems were noted. **(Assignment Specific Question #2c)**

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ASSIGNMENT SPECIFIC QUESTIONS

1. **Please evaluate the firm's Complaint Handling and Medical Device Reporting procedures and any respective complaints related to Riata/Durata perforations.**

The entire complaint file for Riata and Durata leads was reviewed in an Excel spreadsheet that provided all requested data fields. This represented the time period from device approval through June 9, 2009 and totaled 8,463 complaints. For all complaints identified as "perforation, patient", it was indicated that an MDR had been submitted. The FDA adverse event database contains 3,689 MDRs from the firm for these devices during this time period. Complaint review did not identify any adverse events that failed to be reported to FDA as MDRs. Note that the firm currently submits reports electronically on a bi-monthly, rather than 30 day schedule, with the exception of deaths being subject to 30 day reporting timelines. MDR # 2017865-2008-00444 and 2017865-2008-00447 represented Riata perforation events and were submitted to FDA significantly past the mandatory reporting timeframes, although the manufacturer aware date was not reported as delayed. **See Observation #2 for details.**

2. **Please evaluate the firm's CAPA procedures and any respective CAPAs opened to respond to Riata/Durata perforations. Specifically, please evaluate and obtain:**
   a. **Risk management activities related to PIR 04-003 and the Risk Analysis for Riata leads dated 10/18/07.**
   b. **CAPA investigations related to Riata/Durata perforations.**
   c. **Design validations performed that are associated with the following design changes:**
   d. **Meeting minutes from Worldwide Product Disposition Review Board meetings where Riata/Durata perforations were discussed.**
   e. **Additionally, please collect all documentation related to CAPAs opened related to Riata/Durata perforations.**

See the section of CAPA for Question 2a, 2b, 2d and 2e.
See the section of Design Controls for Question 2c.

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3. **Please request device distribution data by Brand/Model and year implanted (2002 to 05/01/08).**

Exhibit #27 is the worldwide distribution data for Riata and Durata leads sorted by Brand/Model through April 2009. Mr. Tsung stated the numbers of implanted leads are almost the same as the numbers of distributed leads because hospitals don't usually keep them in stock.

4. **The following MDR numbers are provided for inspectional review, as the reported event in each case appears to describe perforation, while the problem code designated by the firm was not indicative of perforation, or similar clinical adverse events of tamponade or effusion. It is not known whether these MDR events in fact represented lead perforations, or were included in the firm's calculations for lead perforation occurrence rates that were provided to FDA.**

Prior to the inspection, 32 MDRs were identified from the adverse event database as possible Riata perforation events, and the complaint files for these were requested. Note that these complaint files had to be transmitted to the Sylmar inspection location from their Sunnyvale facility. Review of these complaint files and the associated Medical Device Reports (MDRs) revealed that in some cases the manufacturer has failed to submit MDR reports containing all information reasonably known to them in accordance with the provisions of 21 CFR 803.50(b). Specifically, the complaint files show that complainants reported perforation adverse events for the Riata/Durata device, but these events were not reported as "perforations" in the associated MDRs submitted to FDA by the manufacturer. Perforation was not identified in the submitted 3500A either in the patient or device problem codes. **See Observation #1 for details.**

Bradley Quinn reviewed PIRs 04-003, 09-001, 05-009, 06-005. PIRs 09-001, 05-009, and 06-005 appeared to be adequate. PIR 04-003, Riata Perforations, (**Exhibit #9**) contained three (3) Risk Analyses dated April 28, 2005, October 18, 2007, and March 16, 2009. Each Risk Analysis used a different method for obtaining a Probability of Occurrence. In the April 28, 2005, analysis the firm obtained a Probability of Occurrence value by dividing the number of reports of perforation by the number of leads that had been manufactured. In the October 18, 2007, analysis, the firm obtained a Probability of Occurrence value by dividing the number of reports, both returns and complaints, by the number of leads sold world-wide. In the March 16, 2009 analysis, the firm obtained a

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Probability of Occurrence value by dividing the number of confirmed serious injuries by the number of leads sold world-wide. **See Observation 3 for details.**

5. **Additionally, complaint file for MDR#2017865-2008-01631 is to be reviewed and clarified whether this event represented a perforation. The physician stated he diagnosed the patient's chest pain and reported this as due to perforation, but the MDR as submitted identified only chest pain. Please determine whether this complaint file captures the patient event as both chest pain and perforation, and also compare other complaint files against the MDR report to determine whether complete patient event information has been reported.**

For the specific event reported in 2017865-2008-01631, the physician reported a perforation directly to the firm's field representative (personal communication, September 2008). The field representative communicated with the manufacturer's formal complaint handling unit that the event was loss of capture and the patient experienced chest pain. While these are associated with the perforation event, the manufacturer failed to identify the event as a perforation event in the MDR report. Perforation was identified by the physician during a phone conversation with FDA; he stated this had been communicated to the field representative. Failure to provide complete and accurate event information as reported by the complainant, limits FDA's ability to perform postmarket surveillance.

6. **Further, since perforations, effusions, and tamponade are often clinically related and/or similar events, please evaluate other complaint files for potential singular categorization of the complaint events, and whether any underreporting of these types of adverse events may be occurring.**

Review of the complaint Excel spreadsheet suggests other labels or terms they have used for suspected perforation events are "capture anomaly", patient discomfort", and "dislodgement". Again, the concern is that such events were not included in their risk analysis and rate calculations. **See the sections of Complaint & MDR and CAPA for details.**

MANUFACTURING CODES

The [redacted] (b) (4) [redacted] the lead. The serial number of AHA18963 for an active 65 mm Durata dual shock 7F soft tip curved lead, model 7120, manufactured at the Sylmar facility can be decoded as follows:

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"AHA" (b) (4)
18963 – (b) (4)

Since St. Jude Medical CRMB has other facilities making the same ICD leads, the serial numbers for ICD leads are complex and details of assigning serial number for lead products are explained in the firm's procedure for Label Serial Number, Document 60003059 (**exhibit #28**)."

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

On 7/8/2009, I (Kelvin Cheung) issued an eight-item Inspectional Observation, FDA-483, to Dr. Eric S. Fain – President of ST Jude CRMD. Also participated in the closing meeting from the firm were:

Mr. Daniel J. Starks – Chairman, President and CEO of St. Jude Medical Inc.
Ms. Kathleen M. Chester – Senior VP Regulatory Affairs & QA
Mr. Philip Tsung, Sr. Director of Quality Assurance
Mr. Nestor Kusnierz, Director of Regulatory Compliance

Mr. Bradley Q. Quinn, CSO and Ms. Roberta A. Sullivan, Nurse Consultant were connected via phone to discuss their observations on the FDA-483.

Prior to the FDA-483 discussion, I explained the list represented our observations of objectionable conditions made during the inspection and these conditions might be determined, after review by the Compliance Branch, to be violations of the Federal Food, Drug and Cosmetic Act. I read each observation listed below aloud and provided the firm an opportunity for discussion.

Observations listed on form FDA 483

COMPLAINTS AND MDRS:

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OBSERVATION 1

An MDR report submitted to FDA did not include all information that was reasonably known to the manufacturer.

Specifically, the reviewed complaint files for the following MDRs show that complainants reported adverse events as "perforations" for the Riata/Durata device, but these events were not reported as "perforations" in the associated MDRs submitted to FDA by the manufacturer. "Perforation" was not identified in the submitted 3500A either in the patient or device problem codes.

Date opened	*Serial number*	*MDR Report Number*
11/27/2007	(b) (4)	*2017865-2008-00587*
11/27/2007		*2017865-2008-00488*
11/28/2007		*2017865-2008-00560*
3/5/2008		*2017865-2008-01712*
3/25/2008		*2017865-2008-01631*
4/3/2008		*2017865-2008-01842*
4/7/2008		*2017865-2008-01864*
4/29/2008		*2017865-2008-02290*

Reference: 21 CFR 803.50(b)(1)

Supporting Evidence and Relevance:

Prior to the inspection, 32 MDRs were identified from the adverse event database as possible Riata perforation events, and the complaint files for these were requested. Note that these complaint files had to be transmitted to the Sylmar inspection location from their Sunnyvale facility. Review of these complaint files and the associated Medical Device Reports (MDRs) revealed that in some cases the manufacturer has failed to submit MDR reports containing all information reasonably known to them in accordance with the provisions of 21 CFR 803.50(b). Specifically, the complaint files show that complainants reported perforation adverse events for the Riata/Durata device, but these events were not reported as "perforations" in the associated MDRs submitted to FDA by the manufacturer. Perforation was not identified in the submitted 3500A either in the patient or device problem codes.

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Complaint Date	Serial Number	MDR #	
11/27/2007	(b) (4)	2017865-2008-00587	**Exhibit #29**
11/27/2007		2017865-2008-00488	**Exhibit #30**
11/28/2007		2017865-2008-00560	**Exhibit #31**
3/5/2008		2017865-2008-01712	**Exhibit #32**
3/25/2008		2017865-2008-01631	**Exhibit #33**
4/3/2008		2017865-2008-01842	**Exhibit #34**
4/7/2008		2017865-2008-01864	**Exhibit #35**
4/29/2008		2017865-2008-02290	**Exhibit #36**

Discussion with Management: Ms. Chester stated the firm would review the above MDRs and complaints and respond to the observation in writing.

OBSERVATION 2

[***An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device may have caused or contributed to a death or serious injury.***]

Specifically, MDRs were submitted to FDA significantly past the mandatory reporting timeframes without written explanation. For example:

a) ***MDR # 2017865-2008-00444 indicates a manufacturer aware date and perforation event in 2003, but the 3500A was submitted without explanation to FDA on January 10, 2008.***
b) ***MDR # 2017865-2008-00447 indicates a perforation event date and manufacturer aware date in 2004, but the 3500A was submitted without explanation to FDA on January 10, 2008.***

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Reference: 21 CFR 803.50(a)(1)

Supporting Evidence and Relevance:

Complaints representing events that are MDR reportable were not promptly reviewed, evaluated and investigated by the designated individual per 21 CFR 820.198(d), and MDRs were not submitted within the mandatory reporting timeframes required by 21 CFR 803.50 for device manufacturers. For example, MDR # 2017865-2008-00444 **(exhibit #37)** provides a manufacturer aware date and perforation event in 2003. The 3500A was submitted without explanation to FDA on January 10, 2008. Similarly, MDR # 2017865-2008-00447 **(exhibit #38)** provides a perforation event date and manufacturer aware date in 2004, but the 3500A was also submitted without explanation to FDA on January 10, 2008. These were submitted significantly past the mandatory reporting timeframes.

Discussion with Management: Ms. Chester stated the firm would look into the observation and respond in writing.

CORRECTIVE & PREVENTATIVE ACTIONS:

OBSERVATION 3

The procedures for implementing corrective and preventive actions were not defined.

Specifically, the firm's corrective and preventive action procedure, SOP 3.3.5, Corrective Action and Preventive Action Procedure, Rev. N, references document SOP 4.7.2, Global Risk Management Procedure, for risk analysis activities. SOP 4.7.2 is inadequate in that the procedure does not define the methodology for obtaining the Probability of Occurrence that is used in Risk Evaluations. The lack of definition allows for inconsistent risk analyses to be performed.

For example, the firm used 3 different methodologies for determine Probability of Occurrence in each Risk Analysis performed as part of PIR 04-003. The analyses were conducted on April 28, 2005, October 18, 2007, and March 16, 2009. In the April 28, 2005, analysis the firm obtained a Probability of Occurrence value by dividing the number of reports of perforation by the number of leads that had been manufactured. In the October 18, 2007, analysis, the firm obtained a Probability of Occurrence value by dividing the number of reports, both returns and complaints,

by the number of leads sold world-wide. In the March 16, 2009 analysis, the firm obtained a Probability of Occurrence value by dividing the number of confirmed serious injuries by the number of leads sold world-wide.

Reference: 21 CFR 820.100(a)

Supporting Evidence and Relevance:

We verified that the firm had procedures in place that met the requirements of 21 CFR 820.100(a). However, SOP 4.7.2 – Global Risk Management Procedure (**Exhibit #8**), which defines the Risk Management process as it relates to clinical risk in new product development and throughout the product life cycle, was inadequate in that the procedure did not establish a methodology for obtaining a Probability of Occurrence used in Risk Evaluations. The inadequacy is demonstrated in the firm's three (3) Risk Analysis that were performed as part of the firm's Product Improvement Request (PIR) file, PIR 04-003 (**Exhibit #9**).

Discussion with Management: Mr. Tsung stated there might have been misunderstanding during the inspection and though the firm had already addressed the Investigator's concern. He stated the firm would provide clarifications in the written response. .

RECEIVING INSPECTIONS:

OBSERVATION 4

Sampling methods have not been reviewed for adequacy for their intended use.

Specifically,

[

a) The procedure titled "Receiving Inspection Sampling Program" allows components to be accepted without receiving inspections and review of vendor certificates (Dock to Stock method). The procedure does not have a monitoring program for receiving components that are subject to Dock to Stock method. As of 6/23/09, over (b) (4) *of critical components for defibrillation leads were Dock to Stock components.*

]

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b) The sections of "Dock to Stock General Requirements and "Dock to Stock Part Declassification" were purged without written justifications when it was updated to Revision B on 7/15/2003

Reference: 21 CFR 820.250(b)

Supporting Evidence and Relevance:

During the inspection, I noticed the firm had incorporated a receiving method since 4/2001 that eliminated receiving inspections for "Dock to Stock" components after the vendors provided the component to St. Jude Medical CRMD in certain times without rejections. At that time, the procedure titled "Receiving Inspection Sampling Program" procedure, revision A, **(exhibit #39)** had some general requirements for "Dock to Stock" components" that included reviews of vendor certificates, material certificates and inspection data as well as check for visible damage and configuration. The sections of "Dock to Stock General Requirements and "Dock to Stock Part Declassification" were purged without written justifications when it was updated to Revision B on 7/15/2003. **Exhibit #40** is the change request PD00167 indicating the change of procedure titled "Receiving Inspection Sampling Program" from revision A to revision B. Since the firm considered the procedure as a work instruction document, only the department head was required to approve the change. The firm did not require approvals from production and product development for the change even though the change might have affected production and development if defective "Dock to Stock" components were used in finished leads. As a result, the firm not only does no receiving inspection, but also no reviews of vendor certificates, on approximately (b) (4) of critical components for the manufacture of defibrillation leads as of 6/23/09. The review of FMECA 053 **(exhibit #18)** showed some critical component failures might be caused by vendors and could have been detected from inspection requirements through receiving inspections and reviews of vendor certifications. Mr. Tsung described that the firm has a CAPA system in place to monitor component failures in production and on returned leads, but I explained to the firm's management that the firm does not perform all receiving inspection requirements in production and the failure analysis on returned leads are limited because the returned leads are not always a complete unit. **Exhibit #41** is the current procedure for "Receiving Inspection Sampling Program" procedure, revision D.

Discussion with Management: Mr. Tsung reiterated that the firm's CAPA system is adequate to monitor component failures and stated the firm would respond in writing.

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DESIGN CONTROLS:

OBSERVATION 5

Design reviews were not performed at appropriate times, following the review schedule.

Specifically,

a) ***Design Phase reviews were not conducted as required by the procedure for Global Product Development Protocol and "(b) (4) (b) (4) Product Development Plan, PDP 200102-103." For example: The Global Product Development Protocol and Product Development Plan dated 9/24/01 required phase transition reviews be conducted at the end of each product development phase, but the "Memo to File" written by the Program Manager dated 12/11/02, approximately ten months after the products had been released for distribution, indicated the Phase 3 Transition Review was not required and a combination Phase 2 - Phase 5 Transition Review would be delivered. As of 6/16/09, the firm has not generated the Retrospective Review Report and Project Closeout Report***

b) ***Team meetings, as described in the "(b) (4) (b) (4) Product Development Plan, PDP 200102-103," were not held (b) (4) and team meeting minutes were not maintained in DHF. For instance, the firm recovered only eight weekly team meeting minutes for the entire design development cycle of Vectra Tachy Active Fixation Lead between the period of February 2000 and November 2002.***

c) ***Design Phase reviews were not conducted as required by the procedure for Global Product Development Protocol and (b) (4) (b) (4) For example: The Global Product Development Protocol and Product Development Plan dated 7/11/07 required phase transition review be conducted at the end of product development phase (b) (4) and before the start of phase (b) (4) The firm had decided to divide the entire design project into three submissions: a) softer tip, b) softer tip & curved RV and c) manufacturing improvement, but no Phase 3 Transition Reviews for submissions a & b had been conducted as of 6/24/09 even though the firm started distributing the Riata STS Optim leads with the above modifications after receiving FDA approvals in September 2007 and October 2007.***

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Reference: 21 CFR 820.30(e)

Supporting Evidence and Relevance:

During the review of the DHF for Riata leads models 1580, I noticed that the Program Manager did not have a method such as Gantt chart, metrics or table for keeping track of deliverables and meetings.

a) The Global Product Development Protocol and Product Development Plan dated 9/24/01 required phase transition reviews be conducted at the end of each product development phase, but the "Memo to File" (**exhibit #42**) written by the Program Manager dated 12/11/02, approximately ten months after the products had been released for distribution, indicated the Phase 3 Transition Review was not required and a combination Phase 2 - Phase 5 Transition Review would be delivered. As of 6/16/09, the firm has not generated the Retrospective Review Report and Project Closeout Report. The Global Product Development Protocol, section 10.1.4 and 10.2 required the core team to hold a retrospective review meeting to assess the product development performance against stated goals, project metrics and closeout criteria; and to prepare the Project Closeout Report to confirm fulfillment of all commitments stated in the Product Development Contract.

b) Team meetings, as described in the (b) (4) Product Development Plan, (b) (4) were not held weekly and team meeting minutes were not maintained in DHF. For instance, the firm recovered only eight weekly team meeting minutes for the entire design development cycle of Vectra Tachy Active Fixation Lead between the period of February 2000 and November 2002. Additionally, during the design reviews of FMECA 053 in exhibits #18 & #19, I noticed that there were documented FMECA meetings held in November 2001 (**page 10 – 12 of exhibit #18**), but there were no documented meeting minutes.

c) **Exhibit #22** is a copy of the key milestone update that Mr. Gomperz generated on 6/12/09 and provided to me during the inspection. The review of the table found the firm did not conduct phase reviews as required by the procedure for Global Product Development Protocol and (b) (4) For example: The Global Product Development Protocol and Product Development Plan dated 7/11/07 required phase transition review be conducted at the end of product development phase (b) (4) and before the start of phase (b) (4) The firm had decided to divide the entire design project into three submissions: a) softer tip, b) softer tip & curved RV and c) manufacturing improvement, but no Phase 3 Transition Reviews for submissions a & b had been conducted as of 6/24/09 even though the firm had been distributing the Riata STS Optim leads with the above modifications after receiving FDA approvals in September 2007 and October 2007, respectively. Mr. Gomperz stated he

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was expecting to conduct a phase review for verification & validation after the completion of validation for the submission C.

Discussion with Management: Both Mr. Tsung and Ms. Chester acknowledged the observation and stated the firm would respond in writing. Mr. Tsung asked what kind of corrective actions that the FDA would expect since the design project was completed seven year ago and the firm is in the process of discontinuing the Riata product line. I suggested the firm's management that the firm should conduct retrospective reviews of all DHFs to ensure the required documents have been properly filed.

OBSERVATION 6

Risk analysis is incomplete.

Specifically, the (b) (4) (b) (4) ***' FMECA 053 dated 7/18/2001 was not complete in that not all drawing numbers identified in the section 3.0 " Drawing Reviewed" were reviewed and filed in the report. For example:***

6010977-003	*Poly Sleeve*
6012022-002	*Suture Sleeve*
6042317-001	*Electrode Ring*
6060019-002	*DFT Cable*
7002228-001, 002	*ICD True Bipolar, Dual Shocking Coil Active Lead*

Reference: 21 CFR 820.30(g)

Supporting Evidence and Relevance: During the review of the (b) (4) (b) (4) (b) (4) FMECA 053 dated 7/18/2001 (**exhibit #17**), I noticed that the report did not include all drawings described in the section 3.0. Mr. Tsung and Mr. Gomperz could not explain why those component/drawings were not evaluated for failure mode, effect and criticality analysis. The design FMECA analysis for components and top assembly drawings was part of the risk analysis in the design of the Riata leads.

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Discussion with Management: Mr. Tsung agreed that the analysis of those components were missing from the report FMECA 053 and stated the firm would respond the observation in writing.

OBSERVATION 7

[***Procedures were not established for the validation or verification, review, and approval of design changes before their implementation.***]

Specifically, the firm has no written procedure describing the review and approval process of the design verification plan and report, when design changes require a verification plan. .

Reference: 21 CFR 820.30(i)

Supporting Evidence and Relevance: During the review of the qualification reports, I noticed that the people who reviewed and approved the report were not involved in the design development and they were not the firm's top management who approved the product development plan. According to Mr. Gomperz, the approving individuals who review validation reports are the department heads who are responsible for the validation. Mr. Tsung stated although the firm has no written procedure to identify specific individuals/positions to review and approve validation reports, the Program Manager, who is responsible for the design project, usually makes the determination on the required signatures for validation protocols and reports.

Discussion with Management: Ms Chester asked about what type of corrective actions that the firm should implement. I explained the firm should have a written procedure similar to the procedure for Material Review Board that identify specifics qualified personnel for reviewing and approving validation protocol and reports. Mr. Tsung stated the firm would respond in writing.

OBSERVATION 8

[***Unresolved discrepancies were noted at the completion of the design verification.***]

Specifically, the review of Quality Test Report (QTR) 1403 for Riata Series 1500 showed someone, who reviewed the data sheets, had made a change to the specification of DC resistance measured

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at (b) (4) pin and (b) (4) from (b) (4) ohms to (b) (4) ohms on the Qualification Test Data Sheets for Composite Lead Tensile Test on 1/29/02, but the discrepancy and reason for the change were not discussed in the QTR 1403 or meeting minutes. The specification of DC resistance measured at (b) (4) pin and (b) (4) was later incorporated into product specification P/N PS0069 through ECO AE330 on or about 1/30/02 based on the performance of units in QTR 1403.

Reference: 21 CFR 820.30(f)

Supporting Evidence and Relevance: During the review of the Quality Test Report (QTR) 1403 **(exhibit #19)** for Riata Series 1500, I noticed that someone, who reviewed the data sheets, had made a change to the specification of DC resistance measured at (b) (4) pin and (b) (4) from (b) (4) ohms to (b) (4) ohms on the Qualification Test Data Sheets for Composite Lead Tensile Test on 1/29/02, but the discrepancy and reason for the change were not discussed in the QTR 1403 or meeting minutes. The specification of DC resistance measured at (b) (4) pin and (b) (4) was later incorporated into product specification P/N PS0069 through ECO AE330 on or about 1/30/02 based on the performance of units in QTR 1403. I explained to Mr. Tsung that whoever made the specification change in the report should have written justifications or reasons for the change documented in the report or in the review meeting minute.

Discussion with Management: I explained to the firm's management that this was poor engineering practice that the person who made the change should have explained the reason for the change in the validation report. The firm's management acknowledged the observation and promised to respond in writing.

GENERAL DISCUSSION WITH MANAGEMENT

At the end of the inspection, Mr. Starks asked for suggestions to improve the firm's quality system and reiterated his commitment to comply. Ms. Chester promised to respond to the FDA-483 to the Los Angeles District Office within 15 days.

SAMPLES COLLECTED

Documentary Sample 421779 was collected to establish interstate commerce. It showed St. Jude received a soft tip component from (b) (4) and made an active Durata dual shock 7F soft tip curved RV lead, model 7120/65, S/N AHA18963 with the

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aforementioned soft tip component and shipped the finished device to (b) (6) of (b) (4) (b) (4) via FedEx, tracking # (b) (4) on or about 6/10/2009.

EXHIBITS COLLECTED

1. Floor plan for the ground floor of the plant
2. Organizational chart for key management of CRMD
3. Complaint Handling Procedures, SOP 9.0.4 Rev. N
4. Medical Device Reporting Procedure SOP 9.0.5 Rev. M
5. CD-ROM consisting of an Excel spreadsheet for all complaints for Riata/Durata since 2002
6. Summary of MDRs through February 2009 for Riata & Durata that were related to perforations
7. SOP 3.3.5 – Corrective Action and Preventive Action Procedure, Revision N
8. SOP 4.7.2 – Global Risk Management Procedure, Revision H
9. Product Improvement Request (PIR) file, PIR 04-003
10. list of all CAPAs (PIRs) opened since 2002
11. Product Improvement Request (PIR) file, PIR 05-009
12. World Wide Product Disposition Review Board (WWPDRB) meeting minutes
13. Procedure for "Global Product Development Protocol" Revision C
14. Conceptual Design Review Report dated 4/14/99
15. Product Development Plan, Doc #200102-103, revision 2.00 dated 2/8/00
16. Product Development Plan, Doc #200102-103, revision #2.01 dated 9/23/01
17. FMECA 053 dated 7/18/2001
18. FMECA 053 Addendum 001 dated 1/18/2002
19. Qualification Test Report 1403 dated 1/29/2002
20. Design related changes for Riata lead, model 1580
21. Procedures for "Global Product Development Protocol" Revisions E
22. Key Milestone Update
23. Product Development Plan, revision 1, dated 7/11/07
24. Concept Design Review dated 4/11/07
25. Critical Design Review (DR2)
26. Critical Design Review (DR3)
27. Worldwide distribution data for Riata and Durata leads
28. Procedure for "Label Serial Number"
29. Complaint for S/N (b) (4)

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30. Complaint for S/N (b) (4)
31. Complaint for S/N
32. Complaint for S/N
33. Complaint for S/N
34. Complaint for S/N
35. Complaint for S/N
36. Complaint for S/N
37. Complaint for MDR # 2017865-2008-00444
38. Complaint for MDR # 2017865-2008-00447
39. Procedure titled "Receiving Inspection Sampling Program", revision A
40. Change Request PD00167
41. Procedure for "Receiving Inspection Sampling Program" procedure, revision D
42. "Memo to File" dated 12/11/02

ATTACHMENTS

1. Notice of Inspection, FDA-482, issued to Kathleen M. Chester – Senior VP Regulatory Affairs & QA on 6/8/09
2. Inspection Observations, FDA-483, issued to Dr. Eric S. Fain – President of St. Jude CRMD on 7/8/09
3. DOC 421779
4. FACTS assignment #1042352

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Kelvin Cheung, Investigative Engineer

Bradley Q. Quinn, CSO

Roberta A. Sullivan, Nurse Consultant

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Kelvin Cheung, Investigative Engineer

Bradley Q. Quinn, CSO

Roberta A Sullivan

Roberta A. Sullivan, Nurse Consultant

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